Cue Biopharma Announces Completion of Patient Enrollment in Phase 1b Study of CUE-101 in Combination with KEYTRUDA®

September 26, 2023

- *Completed enrollment of patient expansion cohort of 20 patients at the RP2D of 4 mg/kg in combination with KEYTRUDA® (pembrolizumab) in first line (1L) refractory/metastatic HPV+ Head and Neck Cancer patients*
- *Data to date from CUE-101 in combination with pembrolizumab demonstrates more than double the historical ORR of pembrolizumab alone, including patients with tumors of low PD-L1 expression*
- *Updated data from both the combination and monotherapy trials will be presented at the 2023 Society for Immunotherapy of Cancer (SITC) Annual Meeting being held November 1-5*

BOSTON, Sept. 26, 2023 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical-stage biopharmaceutical company developing a novel class of injectable biologics to selectively engage and modulate disease-specific T cells directly within the patient's body, today announced that it has completed patient enrollment in its Phase 1 clinical trial (NCT03978689) evaluating CUE-101, the company's lead interleukin 2 (IL-2)-based biologic from the CUE-100 series, in combination with KEYTRUDA® (pembrolizumab) as first-line treatment for patients with human papilloma virus positive recurrent/metastatic head and neck squamous cell carcinoma (HPV+ R/M HNSCC).

"Completing the enrollment of the recommended phase 2 dose patient expansion cohort is an important milestone as the data from this trial guides further development plans and associated discussions with the Food and Drug Administration (FDA)," said Daniel Passeri, chief executive officer of Cue Biopharma. "We believe the updated data will build upon the already promising clinical profile established to date, which has shown an enhancement of clinical efficacy with the CUE-101-pembrolizumab combination compared to pembrolizumab alone. With the strength of the data already observed with monotherapy in second line patients and beyond, combined with the promising combination data emerging in 1L with pembrolizumab, we plan to discuss potential registrational paths with the Food and Drug Administration (FDA) for CUE-101 both as a monotherapy and in combination with pembrolizumab, leveraging the Fast Track Designation previously granted to these programs."

Matteo Levisetti, M.D., chief medical officer of Cue Biopharma added, "We believe the data from our CUE-101 trial represents a potential therapeutic breakthrough for HPV+ R/M HNSCC patients, bolstering our confidence in the platform to address unmet needs of patients suffering from a myriad of cancers. The maturing clinical data for CUE-101 further supports the mechanism of action which enables selective expansion of targeted tumor-specific T cells and also provides clinical validation and de-risking of our Immuno-STAT™ platform. This clinical validation is also being supported by a Phase 1 trial with our second CUE-100 series biologic, CUE-102, for Wilms' Tumor 1-expressing tumors. Data to date has demonstrated clinical evidence of anti-tumor activity across multiple indications in patients treated in the dose escalation portion of the study, and we look forward to presenting the data at SITC."

About the CUE-100 Series
The CUE-100 series consists of Fc-fusion biologics that incorporate peptide-MHC (pMHC) molecules along with rationally engineered IL-2 molecules. This singular biologic is anticipated to selectively target, activate and expand a robust repertoire of tumor-specific T cells directly in the patient's body. The binding affinity of IL-2 for its receptor has been deliberately attenuated to achieve preferential selective activation of tumor-specific effector T cells while reducing the potential for effects on regulatory T cells (Tregs) or broad systemic activation, potentially mitigating the dose-limiting toxicities associated with current IL-2-based therapies.

About Cue Biopharma
Cue Biopharma, a clinical-stage biopharmaceutical company, is developing a novel class of injectable biologics to selectively engage and modulate disease-specific T cells directly within the patient's body. The company's proprietary platform, Immuno-STAT ™ *(Selective Targeting and Alteration of T cells)* and biologics are designed to harness the body's intrinsic immune system as T cell engagers without the need for ex vivo manipulation or broad systemic immune modulation.

Headquartered in Boston, Massachusetts, we are led by an experienced management team and independent Board of Directors with deep expertise in immunology and immuno-oncology as well as the design and clinical development of protein biologics.

For more information please visit www.cuebiopharma.com and follow us on Twitter at https://twitter.com/CueBiopharma.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the safe harbor created by those sections. Such forward-looking statements include, but are not limited to, those regarding: the company's plans to present data from its ongoing CUE-101 and CUE 102 clinical trials; the company's belief that the Immuno-STAT platform stimulates targeted immune modulation through the selective engagement of disease-relevant T cells; the company's business strategies, plans and prospects, including potential corporate development opportunities; and the cash runway of the company and the sufficiency of the company's cash, cash equivalents, and marketable securities to fund its operations. Forward-looking statements, which are based on certain assumptions and describe the company's future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "would," "could," "seek," "intend," "plan," "goal," "project," "estimate," "anticipate," "strategy," "future," "likely" or other comparable terms, although not all forward-looking statements contain these identifying words. All statements other than statements of historical facts included in this press release regarding the company's strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Important factors that could cause the company's actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the company's limited operating history, limited cash and a history of losses; the company's ability to achieve profitability; potential setbacks in the company's research and development efforts including negative or inconclusive results from its preclinical studies or the company's ability to replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of its product candidates, its ability to secure required U.S. Food and Drug Administration ("FDA") or other governmental approvals for its product candidates and the breadth of any approved indication; adverse effects caused by public health pandemics, including the recent COVID-19 pandemic, including possible effects on the company's trials; negative or inconclusive results from the company's clinical trials or preclinical studies or serious and unexpected drug-related side effects or other safety issues experienced by participants in clinical trials; delays and changes in regulatory requirements, policy and guidelines including potential delays in submitting required regulatory applications to the FDA; the company's reliance on licensors, collaborators, contract research organizations, suppliers and other business partners; the company's ability to obtain adequate financing to fund its business operations in the future; operations and clinical the company's ability to maintain and enforce necessary patent and other intellectual property protection; competitive factors; general economic and market conditions and the other risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of the company's most recently filed Annual Report on Form 10-K and any subsequently filed Quarterly Report(s) on Form 10-Q. Any forward-looking statement made by the company in this press release is based only on information currently available to the company and speaks only as of the date on which it is made. The company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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